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ture to a lens mold cavity, and initiating polymerization. Photoinitiators, such as those commercially available photoinitiators disclosed above, may be added to the prepolymerization mixture to aid in initiating polymerization. Polymerization may be initiated by a number of well known techniques, which, depending on the polymerizable material, may include application of radiation such as microwave, thermal, e-beam and ultraviolet. A preferred method of initiating polymerization is by application of ultraviolet radiation.

It has been discovered that the ion and/or water permeability of some of the aforementioned core materials may be increased by initiating and completing polymerization in an atmosphere which is substantially free of oxygen. Suitable gases which are readily commercially available include, without limitation thereto, nitrogen and carbon dioxide. Thus, in a preferred embodiment, the oxyperm and ionoperm polymerizable materials are polymerized in an atmosphere having less than about 10000 ppm oxygen. More preferably, the atmosphere surrounding the polymerizable material contains less than about 1000 ppm oxygen. Even more preferably, the surrounding atmosphere contains less than about 100 ppm oxygen, while the most preferred oxygen content is less than about 20 ppm.

In the aforementioned embodiment, the prepolymer mixture must be degassed prior to polymerization. The degassing may be accomplished by a number of techniques known in the art. One technique for degassing the prepolymer mixture involves the use of a series of freezing and thawing steps which are repeated until the appropriate gas concentration level is achieved in the prepolymer mixture. This freeze/thaw method involves cooling the prepolymer mixture until the mixture solidifies, applying a vacuum to the solidified prepolymer mixture, discontinuing the vacuum, and thawing the prepolymer mixture until the mixture is again in liquid form. While this degassing technique is advantageous in a laboratory setting, other degassing techniques known in the art may be more advantageous for commercial lens manufacturing processes.

Alternatively, the atmosphere surrounding the lens mold may include oxygen, under certain conditions. For example, if the lens mold halves seal adequately to one another and the lens mold material has a low rate of oxygen permeability (e.g., polypropylene), it is possible to polymerize a degassed prepolymer mixture in a mold surrounded by ambient air without reaching prepolymer oxygen concentrations sufficiently high to substantially reduce ion or water permeability of the final lens. Thus, in another preferred embodiment of double-sided molding, the lens is formed by the following steps: (1) the prepolymer mixture is degassed, (2) a lens mold half is filled with the prepolymer mixture, (3) the mold halves are sealed to one another, and (4) the polymerization is initiated to form the lens, where the lens mold halves are formed from a material having a low oxygen permeability and steps (2)-(4) may occur in the presence or absence of oxygen. In this embodiment, it is preferred that the lens molds are stored in an inert substantially oxygen-free atmosphere, e.g., nitrogen or carbon dioxide, prior to use.

An essential feature of the manufacturing methods of the present innovative lenses is that a balance of high oxygen permeability and high ion permeability is achieved. Manufacturing techniques and conditions which result in lowering either the oxygen permeability or the ion permeability below levels sufficient to maintain good corneal health and on-eye movement during periods of extended wear are unacceptable to produce the innovative extended-wear contact lenses of the present invention.

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Preferably, the manufacturing method produces a contact lens having a Dk/t of at least 70 barrers/mm and a Ionoton Ion Permeability Coefficient of at least 0.2×10^{-6} cm²/sec. More preferably, the manufacturing method produces a contact lens having a Dk/t of at least 75 barrers/mm and a Ionoton Ion Permeability Coefficient of at least 0.3×10^{-6} cm²/sec. The manufacturing method preferably provides a contact lens having a Dk/t of at least 87 barrers/mm and a Ionoton Ion Permeability Coefficient of at least 0.4×10^{-6} cm²/sec.

The previous disclosure will enable one having ordinary skill in the art to practice the invention. In order to better enable the reader to understand specific embodiments and the advantages thereof, reference to the following examples is suggested. However, the following examples should not be read to limit the scope of the invention.

Examples A-D are arranged in accordance with the materials defined above. Thus, Examples A-1, A-2, etc. relate to Material "A" as defined above. Examples B-1, B-2, etc. relate to Material "B" as defined above. Examples C-1, C-2, etc. relate to Material "C", and Examples D-1, D-2, etc. relate to Material "D". Temperatures are stated in degrees Celsius unless otherwise specified.

Examples E, F and G are directed to demonstrating a correlation between on-eye movement and the Ionoton Ion Permeability Coefficient, the Ionoflux Ion Permeability Coefficient, and the Hydrell Water Permeability Coefficient, respectively.

EXAMPLE A-1

A polysiloxane macromer is prepared by reacting, at room temperature (about 21 C.), one mole equivalent (about 100 grams) of poly(dimethylsiloxane) dialkanol (Shin Etsu Chemical Co., Tokyo, Japan) having hydroxyethyl propoxy end groups with 2 mole equivalents (about 21.2 grams) of isophorone diisocyanate (Aldrich Chemical Co., Milwaukee, Wis.) in the presence of about 0.2 grams dibutyltin dilaurate catalyst (Pfaltz & Bauer, Inc., Waterbury, Conn.). After about 48 hours reaction time, 2.02 mole equivalents (about 38.7 grams) of poly(ethylene glycol) ("PEG", about 610 g/mol Mn, Dow Chemical Corp., Midland, Mich.) and about 0.17 grams of dibutyltin dilaurate (about 0.43% by weight PEG) are added to 80 grams of the reaction product from the prior step. Sufficient chloroform (Aldrich Chemical Co.) is added to the mixture to make the mixture homogeneous. This mixture is stirred at room temperature for about 15 hours. Next, the mixture is stirred for about 8 hours at a temperature of about 44 to 48 C., with the temperature held substantially constant by a surrounding oil bath. The chloroform is then evaporated, in order to achieve a final concentration of about 50% by weight solids, by stirring the mixture at room temperature for about 8 hours. Then, about 2.14 mole equivalents (about 10.4 grams) of isocyanatoethyl methacrylate ("IEM", Monomer Polymer, Inc., Feasterville, Pa.) is added to the mixture. Finally, the mixture is covered with aluminum foil and stirred at room temperature for about 17 hours, yielding a polysiloxane-containing macromer having a number-average molecular weight (Mn) of about 4000 grams per mole.

The macromeric solution is then polymerized, in the presence of about 0.5 weight percent DAROCURO® 1173 photoinitiator (Ciba-Geigy Corporation, Ardsley, N.Y.) to form contact lenses. Polypropylene contact lens molds are filled with the copolymer precursor solution. Ultraviolet light (about 300 to 400 nm) at about 3-6 mW/cm² is applied to the solution in the mold for about 3 hours at room

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temperature. The UV light, in conjunction with the photoinitiator, causes polymerization, thereby allowing the solution to form a contact lens having the shape of the mold. The lenses are extracted with isopropanol to remove the remaining chloroform solvent and any unreacted components. The product is a polysiloxane-containing polymeric contact lens.

Prior to taking oxygen permeability measurements, the lenses are hydrated by placing the lenses in isotonic buffered saline solution for at least eight hours. After hydration, if necessary because of handling, each lens is cleaned with MIRAFLW® Daily Cleaner (CIBA Vision Corporation, Duluth, Ga.) to remove grease and lipids prior to testing. Excess MIRAFLW® cleaner is removed by rinsing with saline or purified water.

Oxygen fluxes (J) are measured at 34 C. in a wet cell (i.e., gas streams are maintained at about 100% relative humidity) using a Dk1000 instrument. Oxygen transmissibility, D_k/t , is determined as outlined in the portions of the specification relating to oxygen permeability and transmissibility.

EXAMPLE A-2

A polysiloxane macromer is first prepared substantially in accordance with the procedure described in Example A-1.

A copolymer precursor solution is prepared by mixing about 180 grams polysiloxane-containing macromer, about 15 grams 3-methacryloxypropyltris (trimethylsiloxy) silane (Shin Etsu), about 4 grams 2-hydroxyethyl methacrylate ("HEMA"), about one gram ethylene glycol dimethacrylate ("EDGMA"), and about one gram DAROCUR® 1173 photoinitiator at room temperature for about 16 hours.

The copolymer precursor solution is then polymerized to form contact lenses. Polypropylene contact lens molds are filled with the copolymer precursor solution. Ultraviolet light (about 300 to 400 nm) at about 3–6 mW/cm² is applied to the solution in the mold for about 3 hours at room temperature. The UV light causes polymerization, thereby allowing the solution to form contact lenses having the shape of the mold. The lens are extracted with isopropanol to remove remaining chloroform solvent and any unreacted components. A preferred resulting polymer contains about 81.8 weight percent polysiloxane macromer, about 13.6% TRIS, about 3.6% 2-hydroxyethyl methacrylate, and about 0.9% EDGMA.

The contact lens is degassed by placing the lens under suitable vacuum for a period sufficient to remove substantially all gas from the lens matrix. Fully hydrated degassed contact lenses having this composition have a Dk of about 87 barrers, a water content of about 19 weight percent, and a modulus of elasticity of about 2.5 MPa.

EXAMPLE A-3

A contact lens is prepared substantially in accordance with the procedure described in Example A-2, but having the final composition of about 19.5 weight percent polysiloxane macromer, about 47% TRIS, and about 33.5% N,N-dimethylacrylamide. Fully hydrated contact lenses having this composition have a Dk of about 49 barrers, a water content of about 30 weight percent, and a modulus of elasticity of about 2.4 MPa.

EXAMPLE A-4

A contact lens is prepared substantially in accordance with the procedure described in Example A-2, but having the final composition of about 30 weight percent polysiloxane

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macromer, about 50% TRIS, and about 20% N,N-dimethylacrylamide. Fully hydrated contact lenses having this composition have a Dk of about 76 barrers, a water content of about 20 weight percent, and a modulus of elasticity of about 1.3 MPa.

EXAMPLE A-5

A contact lens is prepared substantially in accordance with the procedure described in Example A-2, but having the final composition of about 30 weight percent polysiloxane macromer, about 40% TRIS, and about 30% N,N-dimethylacrylamide. Fully hydrated contact lenses having this composition have a Dk of about 55 barrers, a water content of about 30 weight percent, and a modulus of elasticity of about 3.5 MPa.

EXAMPLE A-6

A contact lens is prepared substantially in accordance with the procedure described in Example A-2, but having the final composition of about 30 weight percent polysiloxane macromer, about 60% TRIS, and about 10% N,N-dimethylacrylamide. Fully hydrated contact lenses having this composition have a Dk of about 110 barrers, a water content of about 8.7 weight percent, and a modulus of elasticity of about 2.6 MPa.

EXAMPLE A-7

A contact lens is prepared substantially in accordance with the procedure described in Example A-2, but having the final composition of about 30 weight percent polysiloxane macromer and about 70% TRIS. Fully hydrated contact lenses having this composition have a Dk of about 121 barrers and a water content of about 4.9 weight percent.

EXAMPLE A-8

A contact lens is prepared substantially in accordance with the procedure described in Example A-2, but having the final composition of about 30 weight percent polysiloxane macromer, about 45% TRIS, 5% fluoroacrylate, and about 20% N,N-dimethylacrylamide. Fully hydrated contact lenses having this composition have a Dk of about 6 barrers, a water content of about 20 weight percent, and a modulus of elasticity of about 1.4 MPa.

EXAMPLE A-9

A contact lens is prepared substantially in accordance with the procedure described in Example A-2, but having the final composition of about 82 weight percent polysiloxane macromer, about 14.4% TRIS, and about 3.7% 2-hydroxyethyl methacrylate. Fully hydrated contact lenses having this composition have a Dk of about 96 barrers, a water content of about 19 weight percent, and a modulus of elasticity of about 1.8 MPa.

EXAMPLE A-10

A polysiloxane macromer is prepared substantially in accordance with the procedures described in Example A-1, but the polyethylene glycol has a molecular weight of about 660.

A contact lens is prepared substantially in accordance with the procedure described in Example 2, but having the final composition of about 81.9 weight percent polysiloxane macromer, about 13.6% TRIS, about 3.7% 2-hydroxyethyl methacrylate, and about 0.8% ethylene glycol dimethacrylate.

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late. Fully hydrated contact lenses having this composition have a Dk of about 81 barrers, a water content of about 20 weight percent, and a modulus of elasticity of about 1.4 MPa

EXAMPLE A-11

A contact lens is prepared substantially in accordance with the procedure described in Example A-2, but having the final composition of about 82 weight percent polysiloxane macromer, about 8.6% TRIS, about 4.9% fluoroacrylate, about 3.5% 2-hydroxyethyl methacrylate, and about 1% EDGMA. Fully hydrated contact lenses having this composition have a D_k of about 77 barrers, a water content of about 22 weight percent, and a modulus of elasticity of about 1.3 MPa.

EXAMPLE A-12

A contact lens is prepared substantially in accordance with the procedure described in Example A-1, but the polysiloxane macromer used has hydroxy-sec-butyl end groups as opposed to hydroxyethylpropoxy end groups. The fully hydrated contact lens, after degassing, has a Dk of about 70 barrers, about a 22 weight percent water content, and a modulus of elasticity of about 2.4 Mpa

EXAMPLE B-1

Macromer synthesis

51.5 g (50 mmol) of the perfluoropolyether Fomblin® ZDOL (from Ausimont S.p.A. Milan) having a mean molecular weight of 1030 g/mol and containing 1.96 meq/g of hydroxyl groups according to end-group titration is introduced into a three-neck flask together with 50 mg of dibutyltin dilaurate. The flask contents are evacuated to about 20 mbar with stirring and subsequently decompressed with argon. This operation is repeated twice. 22.2 g (0.1 mol) of freshly distilled isophorone diisocyanate kept under argon are subsequently added in a counterstream of argon. The temperature in the flask is kept below 30° C. by cooling with a waterbath. After stirring overnight at room temperature, the reaction is complete. Isocyanate titration gives an NCO content of 1.40 meq/g (theory: 1.35 meq/g).

202 g of the α,ω -hydroxypropyl-terminated polydimethylsiloxane KF-6001 from Shin-Etsu having a mean molecular weight of 2000 g/mol (1.00 meq/g of hydroxyl groups according to titration) are introduced into a flask. The flask contents are evacuated to approx. 0.1 mbar and decompressed with argon. This operation is repeated twice. The degassed siloxane is dissolved in 202 ml of freshly distilled toluene kept under argon, and 100 mg of dibutyltin dilaurate (DBTDL) are added. After complete homogenization of the solution, all the perfluoropolyether reacted with isophorone diisocyanate (IPDI) is added under argon. After stirring overnight at room temperature, the reaction is complete. The solvent is stripped off under a high vacuum at room temperature. Microtitration shows 0.36 meq/g of hydroxyl groups (theory 0.37 meq/g). 13.78 g (88.9 mmol) of 2-isocyanatoethyl methacrylate (IEM) are added under argon to 247 g of the α,ω -hydroxypropyl-terminated polysiloxane-perfluoropolyether-polysiloxane three-block copolymer (a three-block copolymer on stoichiometric average, but other block lengths are also present). The mixture is stirred at room temperature for three days. Microtitration then no longer shows any isocyanate groups (detection limit 0.01 meq/g). 0.34 meq/g of methacryl groups are found (theory 0.34 meq/g).

The macromer prepared in this way is completely colourless and clear. It can be stored in air at room temperature for

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several months in the absence of light without any change in molecular weight.

EXAMPLE B-2

Macromer synthesis

The first step of the macromer synthesis described under Example B-1 is repeated. An isocyanate titration of the perfluoropolyether reacted with IPDI gives a content of 1.33 meq/g of NCO (theory, 1.35 meq/g).

In a second step, 87.1 g of the α,ω -hydroxypropyl-terminated polydimethylsiloxane TegomerH-Si2111 (Th. Goldschmidt AG, Essen) having a mean molecular weight of 890 g/mol (2.25 meq/g of hydroxyl groups according to titration) are dissolved in 87 ml of toluene. After the reaction has been carried out as indicated under B-1 and the solvent has been removed, a hydroxyl group content of 0.66 meq/g is determined by microtitration (theory 0.60 meq/g). The resultant intermediate is in turn reacted with a stoichiometric amount of isocyanatoethyl methacrylate. Microtitration then no longer shows any isocyanate groups (detection limit 0.01 meq/g). 0.56 meq/g of methacryl groups are found (theory 0.53 meq/g). The macromer prepared in this way is completely colourless and clear and has a long shelf life.

EXAMPLE B-3

Macromer synthesis

The first step of the macromer synthesis described under Example B-1 is repeated, but using a different perfluoropolyether: Fomblin® ZDOLTX (from Ausimont S.p.A., Milan). This material is terminated by $\text{O}-\text{CF}_2-\text{CH}_2-(\text{OCH}_2\text{CH}_2)_n-\text{OH}$ (where $n=0, 1$ or 2). The material used has a mean molecular weight of 1146 g/mol, and contains 1.72 meq/g of hydroxyl groups according to end-group analysis. An isocyanate titration of the perfluoropolyether reacted with IPDI shows a content of 1.23 meq/g of NCO (theory 1.25 meq/g).

In the second step, a stoichiometric amount of Tegomer Hi-Si2111 and toluene are again added. After the reaction has been carried out as indicated under Example B-1 and the solvent has been removed, a hydroxyl group content of 0.63 meq/g is determined by microtitration (theory 0.58 meq/g). The resultant intermediate is in turn reacted with a stoichiometric amount of isocyanatoethyl methacrylate. Microtitration then no longer shows any isocyanate groups (detection limit 0.01 meq/g). 0.55 meq/g of methacryl groups are found (theory 0.51 meq/g). The macromer prepared in this way is completely colourless and clear and has a long shelf life.

EXAMPLE B-4

Macromer synthesis

The first step of the macromer synthesis described under Example B-1 is repeated, but 5.0 g of Fomblin/ZDOL and 2.18 g of IPDI are employed. When the reaction is complete, microtitration shows an isocyanate group content of 1.31 meq/g of hydroxyl groups (theory 1.36 meq/g).

The second step of the synthesis described under Example B-1 is likewise carried out analogously, the stoichiometric ratio between isocyanate-terminated perfluoropolyether and hydroxypropyl-terminated polysiloxane being 2:3. After the reaction has been completed and the solvent has been removed, microtitration shows a content of 0.2 meq/g of hydroxyl groups (theory 0.18 meq/g).

The third step of the synthesis described under Example B-1 is likewise carried out analogously, IEM being

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employed in a precisely stoichiometric ratio. After the reaction, free isocyanate groups can no longer be detected (detection limit 0.01 meq/g). 0.19 meq/g of methacryl groups are found (theory 0.19 meq/g).

EXAMPLE B-5

Production of contact lenses

13.0 g of macromer from Example B-1 are dissolved in 5.6 g of ethanol (Fluka, puriss. p.a.) (70% by weight solution). After complete homogenization of the solution, 5.2 g of 3-tris(trimethylsiloxy)silylpropyl methacrylate (TRIS from Shin-Etsu, product No. KF-2801), 7.8 g of freshly distilled dimethylacrylamide (DMA) and 160 mg of photoinitiator Darocur® 1173 (Ciba) are added. This solution is filtered through a Teflon membrane having a pore width of 0.45 µm under an argon pressure of from 1 to 2 atm. The filtered solution is frozen in a flask in liquid nitrogen, the flask is evacuated under a high vacuum, and the solution is returned to room temperature with the flask sealed. This degassing operation is repeated twice. The flask containing the macromer/comonomer solution is then transferred into a glove box with an inert-gas atmosphere, where the solution is pipetted into dust-free contact-lens moulds made from polypropylene. The moulds are closed, and the polymerization reaction is effected by UV irradiation (15 mW/cm², 5 min.), with simultaneous crosslinking. The moulds are then opened and placed in ethanol, causing the resultant lenses to swell out of the moulds. The lenses are extracted for 24 hours with constantly replenished distilled dichloromethane and subsequently dried in a high vacuum. The dried lenses are equilibrated in phosphate-buffered physiological saline solution in autoclave-resistant vials and then autoclaved at 120° C. for 30 minutes. All physical data measurements are carried out on autoclaved lenses.

The lenses produced in this way are characterized by the following values: oxygen permeability (Dk) 77 barrer (determined by the "wet" method described below), water content of the equilibrated lenses 32 percent by weight, elongation at break at 35° C. 360%, modulus of elasticity 30° C. 0.5 MPa (measured using a Minimat from Polymer Laboratories, UK).

"Wet" measurement of the oxygen permeability:

The oxygen permeability of a material is determined by the coulometric method. To this end, pre-autoclaved lenses are clamped in a holder and then covered on the upper side with a 2 cm layer of water. A gas mixture comprising 21% of oxygen and 79% of nitrogen is passed continuously through the water layer with swirling. The oxygen which diffuses through the lens is measured using a coulometric detector. The reference values are those measured on commercially available contact lenses using this method. Ciba-soft® (CIBA-Vision, HEMA lens) gives a measurement of approx. 7-10 barrer, and Excelens/ (CIBA-Vision, PVA lens) gives a measurement of approx. 22 barrer.

Unfortunately, the oxygen permeability of, for example, contact lenses is frequently given in the literature as a straight Dk value without further definition and frequently without giving any reference material. These are usually values determined on dry material (dry measurement). A comparative measurement of the oxygen permeability of polymer B-5 shows the differences:

- "wet" measurement: 77 barrer
- dry measurement: 158 barrer

EXAMPLE B-6

The process described under Example B-5 for the production of contact lenses is repeated, but the mixture of comonomers has the following composition (in percent by weight):

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55% of macromer from Example B-1
22% of TRIS
22.5% of DMA
0.5% of Blemer® QA

EXAMPLE B-7

The process described under Example B-5 for the production of contact lenses is repeated, but the mixture of comonomers has the following composition (in percent by weight):

55% of macromer from Example B-1
22% of TRIS
23% of DMA

EXAMPLE B-8

Analogously to EXAMPLE B-5 (in weight percent):
40% of macromer from Example B-1
30% of TRIS
30% of DMA

EXAMPLE B-9

The process described under B-5 for the production of contact lenses is repeated, but a 70% by weight solution of the macromer in toluene is used instead of the 75% by weight solution in ethanol described above. The mixture of comonomers has the following composition (in percent by weight):

55% of macromer from Example B-1
22% of TRIS
23% of DMA

EXAMPLE B-10

The process described under B-5 for the production of contact lenses is repeated, but a 70% by weight solution of the macromer in octamethylcyclotetrasiloxane is used instead of the 75% by weight solution in ethanol described above. The mixture of comonomers has the following composition (in percent by weight):

55% of macromer from Example B-1
22% of TRIS
23% of DMA

Physical measurement data for the contact-lens material from Examples B-5 to B-10 (O₂ Dk value, wet method) are presented in TABLE B-I:

TABLE B-I

Example	Water Content (%)	DK (barrer)	Modulus of Elasticity (MPa)	Elongation at Break (%)
B-5	32	77	0.5	360
B-6	23.8	110	1.1	160
B-7	19.5	110	0.6	130
B-8	30.9	81	0.3	300
B-9	30			
B-10	25			

EXAMPLE B-11

About 10.0 grams of macromer from Example B-1 are dissolved in 3.3 grams of ethanol (Fluka, puriss. p.a.). After complete homogenization of the solution, about 4.0 grams of 3-tris(trimethylsiloxy)silylpropyl methacrylate (TRIS, from Shin-Etsu, product no. KF-2801), about 5.9 g. freshly di

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titled dimethylacrylamide (DMA), about 0.1 g. Blemer® QA (a methacrylate having quaternary ammonium substituents, Linz Chemie) and about 100 mg of photoinitiator Darocur® 1173 (Ciba) are added. The solution is filtered through a TEFLON membrane having a pore width of 0.45 mm under an argon pressure of from about 1 to 2 atm.

The filtered solution is frozen in a flask in liquid nitrogen, the flask is evacuated under a high vacuum, and the solution is returned to room temperature with the flask sealed. This degassing operation is repeated twice. The flask containing the macromer/comonomer solution is then transferred into a glove box with an inert gas atmosphere, where the solution is pipetted into dust-free, polypropylene contact lens molds. The molds are closed, and the polymerization reaction is effected by UV irradiation, with simultaneous crosslinking. The molds are then opened and placed in isopropyl alcohol, causing the resultant lenses to swell out of the molds. The lenses are extracted for about 24 hours with nearly continuous replenishing of isopropyl alcohol. Subsequently, the lenses are dried under high vacuum.

The dried contact lenses are equilibrated in autoclave-resistant vials in phosphate-buffered physiological saline solution, and then autoclaved for 30 minutes at about 120° C. Physical measurement data for the autoclaved lens is presented below:

Dk [barrer]:	93
water content [%]:	20.3%
modulus of elasticity [Mpa]:	0.96

EXAMPLE B-12

Lenses are prepared in accordance with the procedures described in Example B-11, but are subsequent surface treated as follows. The dried lenses are transferred into a plasma coating apparatus wherein they are surface treated in a methane/“air” mixture (“air”, as used here, denotes 79% nitrogen and 21% oxygen) for a period of about 5 minutes. The apparatus and plasma treatment process have been disclosed by H. Yasuda in “Plasma Polymerization”, Academic Press, Orlando, Fla. (1985), pages 319 forward.

The plasma-treated contact lenses are equilibrated in autoclave-resistant vials in phosphate-buffered physiological saline solution, and then autoclaved for 30 minutes at about 120° C. Physical measurement data for the plasma-coated autoclaved lens is presented below:

Dk [barrer]:	88
water content [%]:	21.8%
modulus of elasticity [Mpa]:	1.03

EXAMPLE B-13

Lenses are prepared in accordance with the procedures described in Example B-5, but the mixture of comonomers has the following composition, in weight percentages:

Macromer of Example B-1:	60%
TRIS:	25%
DMA:	15%

EXAMPLE B-14

Lenses are prepared in accordance with the procedures described in Example B6, with the same comonomer

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composition, but the comonomers are dispensed into dust-free contact lens molds in ambient air atmosphere.

EXAMPLE C-1

Reaction of α,ω -bis-aminopropyl-dimethylpolysiloxane with D(+)-gluconic acid d-lactone:

Before the reaction, the amino-functionalized polydimethylsiloxane employed for the synthesis (X-22-161-C, Shin Etsu, JP) was finely dispersed in acetonitrile, extracted and then subjected to molecular distillation.

The following reactions take place with exclusion of H₂O. 200 g of purified amino-functionalized polydimethylsiloxane (0.375 meq of NH₂/g; Mn(VPO) 3400–3900 (VPO, Vapour Pressure Osmometry)), dissolved in 200 ml of absolute THF, are slowly added dropwise to a suspension of 13.35 g (75 mmol) of D(+)-gluconic acid d-lactone in 50 ml of absolute THF and the mixture is stirred at 40° C. for about 24 hours until the lactone has reacted completely. (Monitoring of the reaction by thin layer chromatography (TLC): silica gel; i-propanol/H₂O/ethyl acetate 6:3:1; staining with Ce(IV) sulfate/phosphoromolybdic acid solution (CPS reagent)). After the reaction, the reaction solution is concentrated to dryness and the residue is dried under 3 Pa (0.03 mbar) for 48 hours. 213.3 g of α,ω -bis-(3-gluconamidopropyl)poly-dimethyl are obtained. Titration of the amino groups with perchloric acid shows a conversion of the amino groups of more than 99.8%.

Reaction of α,ω -bis-3-gluconamidopropyl-dimethylpolysiloxane with IEM

The product obtained above (213.3 g) is dissolved in 800 ml of absolute THF and the solution is heated to 40° C. with the addition of catalytic amounts of dibutyltin dilaurate (DBTDL). 14 g (90 mmol) of IEM in 20 ml of absolute THF are added dropwise to this solution over a period of about 4 hours. This corresponds to a concentration of 1.2 equivalents of IEM per gluconamide unit. The reaction is carried out in the course of 48 hours (monitoring of the reaction by IR spectroscopy detection of the NCO ties). The reaction solution is concentrated and the product is dried in a brown glass flask under 3 Pa (0.03 mbar) for 24 hours, while cooling with ice. 227.2 g of a colourless rubber-elastic product of high optical transparency remain.

EXAMPLE C-2 to C-7

Further amino propyl-dimethylpolysiloxanes (PDMS) are reacted with a different amount of gluconolactone and concentrations of IEM analogously to Example C-1. The examples are summarized in Table C-I

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TABLE C-I

Example	Name	Type	Mn	NH ₂ *	Amount of batch		
					PDMS g(mmol) of NH ₂	Glu g(mmol)	IEM g(mmol)
C-1	X-22-161-C	term.	3400	2	200 (75)	13.4 (75)	14.0 (90.0)
C-2	X-22-161-C	term.	3400	2	200 (74)	13.4 (75)	25.7 (165.0)
C-3	X-22-161-C	term.	3400	2	200 (75)	13.4 (75)	29.2 (187.5)
C-4	PS 813	pen.	1200	1			
C-5	GP 4	pen.	3150	2.6			
C-6	GP 6	pen.	5960	3			
C-7	KF 8003	pen.	9700	4.7	200 (98)	17.5 (98)	18.2 (117.4)

Legend:

X-22-161-C and KF 8003 are products from Shin Etsu (Japan), PS813 is a product from Petrarch-H Is, GP4 and GP6 are products from Genesee.

*Amino groups per macromer chain

Glu:D(+) gluconic acid d-lactone

term: terminal

pen: pendent

EXAMPLE C-8

The reaction is carried out in accordance with Example C-1, but instead of D(+)gluconic acid d-lactone, 75 mmol of lactobionic acid 1,5-lactone, suspended in 50 ml of absolute THF, are added dropwise to a solution of amino-functionalized polydimethylsiloxane (X-22-161-C) in 180 ml of absolute THF and 20 ml of DMSO (pure, 99%). Titration of the amino groups with perchloric acid indicates a reaction conversion of 99% (<0.01 meq of NH₂/g). Here also, a colourless optically clear macromer is obtained.

EXAMPLE C-9 and C-10

The reactions are carried out analogously to Example C-1. However, the catalyst necessary for addition of the isocyanate onto the hydroxyl groups is varied. Instead of DBTDL, catalytic amounts of 1,4-diazabicyclo[2.2.2]octane (DABCO) or 4-dimethylamino-pyridine (DMAP) are added and the reaction is continued as described under Example C-1. In both cases, an optically clear, colourless rubber-elastic macromer results in a manner corresponding to Example C-1

EXAMPLE C-11

The reaction is carried out analogously to Example C-1. In a manner corresponding to Example C-8, 0.1 mol of lactobionic acid 1,5-lactone is suspended in 50 ml of absolute THF and the suspension is added dropwise to a solution of amino-functionalized polydimethylsiloxane (KF-8003) in 180 ml of absolute THF and 20 ml of DMSO (pure, 99%). The reaction time is increased to about 48 hours. A residual content of 0.07 meq of NH₂/g can be detected, and is reacted completely by addition of the corresponding molar amount of D(+)gluconic acid d-lactone to the reaction solution. The colourless highly transparent product has a residual content of amino groups of <0.01 meq/g.

EXAMPLE C-12

52.09 g (9.78 mmol) of purified amino-functionalized polydimethylsiloxane (X-22-161-C, Shin Etsu JP), dissolved in 110 ml of absolute THF, are initially introduced

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into the reaction vessel under an inert gas atmosphere, and 1.14 g (6.52 mmol) of D-glucaro-1,4:6,3-dilactone, dissolved in 20 ml of absolute THF, are added. The reaction solution is stirred at room temperature for 15 hours and then worked up in a manner corresponding to Example C-1. The amine content is 0.134 meq/g. The terminal amino groups of the resulting penta-block macromer are reacted with gluconolactone in the following reaction step. 41.84 g (5.146 meq of NH₂) of the above macromer and 0.917 g (5.15 mmol) of D(+)gluconic acid d-lactone are suspended in 300 ml of absolute THF and the suspension is stirred under nitrogen at 40° C. for 18 hours. The filtered solution is then concentrated and the residue is dried under 3 Pa (0.03 mbar) for 48 hours. A highly viscous optically clear substance having a residual content of amino groups of 0.01 meq/g results.

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EXAMPLE C-13**Preparation of an amino- and perfluoroalkyl-functionalized polydimethylsiloxane:**

3.0 ml of absolute toluene are added to 15 g of polydimethylsiloxane-co-methylhydrosiloxane [Bayer Silopre U-230; 10,000 g/mol; 2.3 mmol of Si—H/g], and 1.72 g (9. mmol) of allylphthalimide [CAS Reg. No. 5428-09-1] are then added. The mixture is frozen several times and the flask evacuated and then brought to room temperature again. The flask is then let down with argon. 0.7 ml of a 0.005 mol solution of Lamoreaux catalyst (prepared in accordance with U.S. Pat. No. 3,220,972. General Electric) in absolute toluene (100 ppm of Pt/mol of Si—H) is added and the mixture is heated to 80° C. After a reaction time of half an hour, colourless, clear to slightly cloudy solution, the ¹H-NMR spectrum of which no longer shows resonances of allyl hydrogen atoms, is obtained.

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Thereafter, 6.2 g (15.3 mmol) of degassed allyl 1H,11 2H,2H-perfluorooctyl ether are slowly added and the mixture is stirred at 80° C. for 2 hours. A ¹H-NMR spectrum now shows a severely weakened resonance of the Si—function at 4.6 ppm and an intense resonance at 0.5 ppm which originates from Si—CH₂ hydrogen atoms.

3.0 ml of 1-hexene are then added in order to react the remaining excess of Si—H groups, which could otherwise

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cause crosslinking of the polymer when air later has access. The mixture is further stirred at 80° C. for another half an hour. The reaction mixture is then left to stand overnight. The product is purified over a silica gel column with hexane/ethyl acetate (3:2), the solvent is stripped off and the macromer is dried under a high vacuum. A colourless, clear, viscous product is obtained. The macromer purified in this way is taken up in 20 ml of hexane, 20 ml of methylamine [33% in ethanol] are added and the mixture is heated to 40° C. After 10–15 minutes, a white voluminous precipitate separates out. After 30 minutes, the suspension is cooled and filtered and the precipitate is washed with a little hexane. The filtrate is evaporated and the residue is then dried under a high vacuum. Thereafter, the content of amino groups is determined by titrimetry (perchloric acid).

The resulting macromer is clear and viscous. The amino group content is 78.6% of theory. The total yield of macromer after the chromatographic purification is 75%.

Preparation of a gluconamide

17.3 g (corresponding to an amine content of 5.4 meq) of this aminoalkyl-substituted product are dissolved in 20 ml of dried THF. The solution is repeatedly frozen, degassed and let down with argon. All the following operations are carried out in an argon atmosphere. 712 mg of D(+)-gluconic acid d-lactone (4 mmol) are then added. Because of the low solubility of the lactone, a suspension is initially obtained. After stirring overnight at 50° C., the solution is clear and the lactone has been used completely. The stoichiometric remaining amount of D(+)-gluconic acid d-lactone (260 mg, 1.46 mmol) is then added and the mixture is stirred again at 50° C. overnight. A trace of unreacted lactone is observed. Completion of the reaction is monitored by means of thin layer chromatography on silica gel plates with the mobile

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Example C-1 are transferred to a round-bottomed flask with a nitrogen attachment, degassed under 3 Pa (0.03 mbar) for 24 hours and then dissolved in 2.7 g of ethanol which has been flushed with N₂ for half an hour beforehand. The subsequent preparation of samples and the polymerization are carried out inside a glove box with exclusion of oxygen. The above monomer mixture and the macromer solution from Example C-1 are mixed, with the addition of 0.012 g (0.21 mmol) of Darocur® 1173 and the mixture is subjected to microfiltration (0.45 mm filter). 180 µl of this mixture are introduced into a polypropylene mould, which is then closed with an appropriate lid of polypropylene. The mixture is then irradiated with a UV-A mercury high pressure lamp in a nitrogen atmosphere in a UV oven equipped for this for 5 minutes. The lamps (5 each of the brand TLK40W/10R, Philips) are above and below the holder inserted. The irradiation intensity is 14.5 mW/cm².

The polypropylene mould is opened and the finished discs or lenses are removed by soaking by means of a solvent mixture of methylene chloride and ethanol (2:3). The lenses and discs are extracted in ethanol at room temperature in special polypropylene cages for 48 hours and then dried at 40° C. under 10 Pa (0.1 mbar) for 24 hours (autoclaving at 120° C., 30 minutes). The discs show an E modulus of 1.1 MPa, a permeability to oxygen of 183 barrier and a hardness (Shore A) of 53.

EXAMPLE C-15 to C-19

Further polymers are prepared in a manner corresponding to Example C-14 (composition in percentages by weight). Table C-II shows examples C-15 to C-19 and the properties of the resulting materials measured on discs.

TABLE C-II

Example	Water Content [%]	Macromer from Example	Macromer weight percent	DMA weight percent	DMEA weight percent	TRIS weight percent	E modulus [Mpa]	Dk [barrier]
C-15	not measured	C-3	32.8	—	30	37.2	—	—
C-16	19.9	C-3	32.9	34.3	—	32.7	0.7	84
C-17	25.1	C-3	39.3	34.3	—	36.4	0.9	72
C-18	17.5	C-3	35.7	34.3	—	30.0	0.7	100
C-19	23.4	C-3	33.3	33.3	—	33.4	0.7	96

Legend:

DMA: N,N-Dimethylacrylamide

TRIS: 3-Methacryloyloxypropyl-tris(trimethylsilyloxy)silane

DMEA: 2-Dimethylaminoethyl acrylate

phase 1-propanol/ethyl acetate/water (6:1:3). The silica gel plates are developed by means of Ce(IV) sulfate/phosphoromolybdic acid solution. Subsequent titration on amino groups yields a residual amino content of <0.1%. After filtration and removal of the solvent by distillation, a highly viscous clear macromer with 0.295 mequivalent of gluconamide per gram of macromer is obtained.

EXAMPLE C-14

Before the polymerization, the acrylates employed, isobutyl acrylate (IBA), N,N-dimethylacrylamide (DMA) and 3-methacryloyloxypropyl-tris(trimethylsilyloxy)silane (TRIS) are each freed from inhibitors by distillation. 0.32 g (2.76 mmol) of IBA, 0.80 g (8.1 mmol) of DMA and 1.44 g (3.4 mmol) of TRIS are weighed into a 50 ml round-bottomed flask and the flask is flushed with N₂ for half an hour, while cooling with ice. 1.44 g of macromer from

EXAMPLE C-20

Uncoated contact lens

A contact lens is prepared in a manner corresponding to Example C-14, using the Example C-3 macromer, with the following composition in percentages by weight:

Macromer:	33.3
DMA:	33.3
TRIS:	33.4

The lens has a Dk of about 94 and a water content of about 20.0 weight percent. The results are presented in TABLE C-III for comparison with coated lens properties.

EXAMPLE C-21

Plasma-treated contact lens

Dried lenses prepared in accordance with the procedures described in Example C-20 are transferred into a plasma

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coating apparatus where the lenses are surface treated in a methane/"air" mixture ("air", as used here, denotes 79% nitrogen and 21% oxygen). The apparatus and plasma treatment process have been disclosed by H. Yasuda in "Plasma Polymerization", Academic Press, Orlando, Fla. (1985), pages 319 forward.

The dried plasma-treated contact lenses are equilibrated in autoclave-resistant vials in phosphate-buffered physiological saline solution, and then autoclaved for 30 minutes at about 120° C. The plasma-treated autoclaved lens has a Dk (barrer) of 90 and a water content of 21.5%. The results are presented in TABLE C-III for comparison with coated lens properties.

TABLE C-III

Example	Surface type	Dk [barrer]	Water content [%]
C-20	untreated	94	20.0
C-21	plasma-treated	90	21.5

EXAMPLE C-22

The synthesis of this polymer corresponds to Example C-14 with the following comonomer composition: Example C-3 macromer/TRIS/DMA: 32.8%/32.6%/34.2% (in percentages by weight) and an addition of 0.4% by weight of trimethylammonium-2-hydroxypropyl methacrylate hydrochloride (Blemer® QA, Nippon Oil Corp.). The polymer has a modulus of 0.9 MPa and a permeability to oxygen of 82 barrer. The water content is 25.1% (after 30 minutes' autoclaving at 120° C.). For comparison, Example C-16 has a water content of 20% with a very similar comonomer composition (no addition of Blemer® QA).

EXAMPLE C-23

The polymer is prepared analogously to Example C-14, but the polymerization is carried out in bulks which means without addition of ethanol. The composition of the comonomers and the material properties of the polymer synthesized, measured on discs is given below.

Example C-7 macromer:	41%
IBA:	23%
1-vinyl-2-pyrrolidone (NVP):	24%
acrylonitrile (AN):	12%
Hardness (shore A):	68

EXAMPLE C-24

The polymerization is carried out in accordance with Example C-14 but with the following changed comonomer composition:

macromer of Example C-7/IBA/TRIS 20%/19%/60% and 1% (in percentages by weight) of bis(3-methacryloyloxypropyl)tetramethyldisiloxane.

An optically clear polymer with an E modulus of 0.4 MPa, a permeability to oxygen of 241 barrer and a hardness (Shore A) of 42 is obtained.

EXAMPLES C-25 through C-27

Contact lenses are prepared in accordance with the procedure described in Example C-14. The compositions in weight percentages are as follows:

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Ex-ample	Macro-mer	Macromer weight percent	IBA weight percent	DMA weight percent	TRIS weight percent	HFBA weight percent
C-25	C-3	36.0	8.0	20.0	36.0	—
C-26	C-2	35.0	5.0	20.0	35.0	5.0
C-27	C-3	32.8	—	30.0	37.2	—

where IBA is isobutylacrylate.

DMA is N,N-Dimethylacrylamide

TRIS is 3-methacryloyloxypropyl-tris(trimethylsiloxy)silane

HFBA is acrylsäure-2,2-3,4,4,4-hexafluorbutylacrylate.

EXAMPLE C-28

The polymerization is carried out in accordance with Example C-14 but with the following changed comonomer composition: macromer of Example C-1/DMA/TRIS 33.3%/33.3%/33.3%. An optically clear polymer is obtained.

EXAMPLE D-1

Macromer Synthesis

In a dry box under nitrogen atmosphere, about 200 grams of dry PDMS dipropoxyethanol (Shin-Etsu) is added to a container. Isocyanatoethyl methacrylate (IEM) in an amount equal to about 2 moles per mole PDMS dialkanol is added to the container. About 0.1 weight percent dibutyltin dilaurate (DBTL) catalyst, based on PDMS dialkanol weight, is added to the container along with a stir bar. The container is immersed in an oil bath atop a stir plate, and secured in place with a clamp. A stream of UPC air at about 2 psig is passed over the mixture. The mixture is agitated at room temperature (about 22° C.) for about 24 hours. An iterative procedure follows in which the mixture is analyzed for isocyanate content and IEM is added if the PDMS dialkoxyalkanol has not been completely reacted. The mixture is stirred about 24 hours more. The macromer produced is a siloxane containing macromer.

EXAMPLE D-2

Lens fabrication

A prepolymerization mixture is prepared by mixing about 56 grams of the macromer from Example D-1, about 1 gram of TRIS, about 29 grams N,N-dimethylacrylamide (DMA), about 1 gram methacrylic acid, about 0.5 gram Darocur® 1173 photoinitiator, and about 20 grams hexano. The mixture is agitated for about 20 minutes at room temperature.

Next, the mixture is degassed via a series of freezing and thawing steps. The container is placed in a liquid nitrogen bath until the mixture solidifies. A vacuum is applied to the container at a pressure of about 200 millitorr or less for about 5 minutes. Then, the container is placed in a bath of room temperature water until the mixture is liquid again. This process is performed a total of three times.

The mixture is then polymerized to form contact lenses. The prepolymerization mixture is poured into polypropylene contact lens molds in a nitrogen atmosphere. The polymerization is effected by applying UV radiation (about 4 mW/cm²) for a period of about 15 minutes.

The resulting fully hydrated contact lens has a water content of about 23%. The lens has a Dk of about 115 barrer and a modulus of elasticity of about 2 MPa

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EXAMPLE D-3

Lens fabrication

A contact lens is prepared in accordance with the procedure described in Example D-2, with the difference being that the composition is about 50% macromer of Example D-1, about 20% TRIS and about 30% DMA.

The resulting fully hydrated contact lens has a water content of about 20%. The lens has a Dk of about 118 barrers and a modulus of elasticity of about 1.8 Mpa.

EXAMPLE E-1

Material A

A contact lens is prepared substantially in accordance with the procedure described in Example A-2. Prior to polymerization, the prepolymerization mixture is degassed by cooling the prepolymer mixture with liquid nitrogen until the mixture solidifies and is near liquid nitrogen temperature, then applying a vacuum (about 0.1 mm Hg) to the solidified prepolymer mixture, discontinuing the vacuum, and thawing the prepolymer mixture until the mixture is again in liquid form. This degassing procedure is performed a total of three times on the prepolymerization mixture.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. The cured lens has an equilibrium water content of about 19%. Subsequent to curing, the lens is plasma treated for about 10 minutes in an atmosphere of methane and air at a 2:1 CH₄:air volume:volume ratio. The working pressure of the gas is about 50 millitorr. The plasma treatment is accomplished in a Plasma Polymerization Apparatus LCVD-20-400A (Plasmacarb, Bedford, Mass.).

The Ionoton Ion Permeability Coefficient of the lens is 0.81×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-2

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-10. Prior to polymerization, nitrogen gas is bubbled through the prepolymer mixture in order to remove oxygen from the prepolymer mixture.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. The cured lens has an equilibrium water content of about 26 weight percent. No coating is applied to the surface.

The Ionoton Ion Permeability Coefficient of the lens is -0.063×10^{-3} cm²/sec. Clinical examination shows that the lens does not move on the human eye. See Table E for a summary of the results.

EXAMPLE E-3

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-12. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. The cured lens has an equilibrium water content of about 30 weight percent. Subsequent to

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curing, the lens is plasma treated for about 3 minutes in an atmosphere of methane and air at a 2:1 CH₄:air volume ratio.

The Ionoton Ion Permeability Coefficient of the lens is 0.50×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-4

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-12. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. The cured lens has an equilibrium water content of about 30 weight percent. Subsequent to curing, the lens is plasma treated for about 5 minutes in an atmosphere of methane and air at a 2:1 CH₄:air volume ratio.

The Ionoton Ion Permeability Coefficient of the lens is 0.47×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-5

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-12. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. The cured lens has an equilibrium water content of about 30 weight percent. Subsequent to curing, the lens is plasma treated for about 7.5 minutes in an atmosphere of methane and air at a 2:1 CH₄:air volume ratio.

The Ionoton Ion Permeability Coefficient of the lens is 0.35×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-6

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-11. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. The cured lens has an equilibrium water content of about 30 weight percent. The lens is not subsequently coated.

The Ionoton Ion Permeability Coefficient of the lens is 1.1×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-7

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-21. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

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The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. Subsequent to curing, the lens is plasma treated for about 5 minutes in an atmosphere of methane and air at a 2:1 CH₄:air volume ratio.

The Ionoton Ion Permeability Coefficient of the lens is 2.9×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-8

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-21. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. Subsequent to curing, the lens is plasma treated for about 7.5 minutes in an atmosphere of methane and air at a 2:1 CH₄:air volume ratio.

The Ionoton Ion Permeability Coefficient of the lens is 0.25×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-9

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-20. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in an air atmosphere to form the contact lens. Subsequent to curing, the lens is not surface treated.

The Ionoton Ion Permeability Coefficient of the lens is 0.008×10^{-3} cm²/sec. Clinical examination shows that the lens does not move on the human eye. See Table E for a summary of the results.

EXAMPLE E-10

Material D

A contact lens is prepared substantially in accordance with the procedure described in Example D2. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. Subsequent to curing, the lens is not surface treated.

The Ionoton Ion Permeability Coefficient of the lens is 1.4×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

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EXAMPLE E-11

Material D

A contact lens is prepared substantially in accordance with the procedure described in Example D-2. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. Subsequent to curing, the lens is plasma treated for about 7.5 minutes in an atmosphere of methane and air at a 2:1 CH₄:air volume ratio.

The Ionoton Ion Permeability Coefficient of the lens is 0.61×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-12

Material D

A contact lens is prepared substantially in accordance with the procedure described in Example D-2. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in a nitrogen atmosphere to form the contact lens. Subsequent to curing, the lens is plasma treated for about 5 minutes in an atmosphere of methane and air at a 2:1 CH₄:air volume ratio.

The Ionoton Ion Permeability Coefficient of the lens is 1.5×10^{-3} cm²/sec. Clinical examination shows that the lens moves on the human eye. See Table E for a summary of the results.

EXAMPLE E-13

Material D

A contact lens is prepared substantially in accordance with the procedure described in Example D-2. Prior to polymerization, the prepolymerization mixture is degassed by the repeated freeze/thaw procedure of Example E-1.

The prepolymer mixture is cured in an air atmosphere to form the contact lens. Subsequent to curing, the lens is not surface treated.

The Ionoton Ion Permeability Coefficient of the lens is -0.001×10^{-3} cm²/sec. Clinical examination shows that the lens does not move on the human eye. See Table E for a summary of the results.

TABLE E

Example	Material	Degassing	Curing atmosphere	Surface treatment CH ₄ :air plasma (minutes)	Ionoton Ion Permeability Coefficient (10 ⁻³ cm ² /sec)	On-eye Movement
E-1	A	3-cycle freeze/thaw	nitrogen	10	0.81	YES
E-2	B	nitrogen bubble	nitrogen	no plasma	-0.063	NO

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TABLE E-continued

Example	Material	Degassing	Curing atmosphere	Surface treatment CH ₄ :air plasma (minutes)	Ionoton Ion Permeability Coefficient (10 ⁻³ cm ² /sec)	On-eye Movement
E-3	B	3-cycle freeze/thaw	nitrogen	3	0.50	YES
E-4	B	3-cycle freeze/thaw	nitrogen	5	0.47	YES
E-5	B	3-cycle freeze/thaw	nitrogen	7.5	0.35	YES
E-6	B	3-cycle freeze/thaw	nitrogen	no plasma	1.1	YES
E-7	C	3-cycle freeze/thaw	nitrogen	5	2.9	YES
E-8	C	3-cycle freeze/thaw	nitrogen	7.5	0.25	YES
E-9	C	3-cycle freeze/thaw	air	no plasma	0.008	NO
E-10	D	3-cycle freeze/thaw	nitrogen	no plasma	1.4	YES
E-11	D	3-cycle freeze/thaw	nitrogen	7.5	0.61	YES
E-12	D	3-cycle freeze/thaw	nitrogen	5	1.5	YES
E-13	D	3-cycle freeze/thaw	air	no plasma	-0.001	NO

Considering Examples E-1 through E-13 of Table E, the lowest value of Ionoton Ion Permeability Coefficient for which a lens moves on the eye is 0.25×10^{-3} cm²/sec. The highest value of Ionoton Ion Permeability Coefficient for a lens which bound on the eye is 0.008×10^{-3} cm²/sec. Thus, a contact lens preferably has an Ionoton Ion Permeability Coefficient greater than about is 0.008×10^{-3} cm²/sec., more preferably greater than about 0.25×10^{-3} cm²/sec.

EXAMPLE F-1

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-25. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 0 mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone (PVP) in accordance with the following procedure, using a glass plasma reactor equipped with an external ring electrode and a 27.13 MHz radio frequency (RF) generator for the generation of an inductively-coupled, cold glow discharge plasma. Highly purified argon is used as a plasma gas and as a carrier gas for N-vinylpyrrolidone (NP) monomer feed. The NVP feed line is located about 10 cm below the glow zone.

The contact lens is placed in the 20 cm diameter plasma reactor at a position about 15 cm below the plasma glow one. The reactor is then evacuated for about 30 minutes to about 0.009 mbar. Subsequent to evacuation, the plasma gas flow is set to 20 sccm (standard cubic centimeters), the glow discharge is started at a pressure of about 0.15 mbar and maintained for about one minute at a power of about 170 Watts (in order to clean and activate the lens surface). After reduction of argon plasma gas flow to about 10 sccm, the argon carrier gas flow for the NVP monomer is also set to 10 sccm. The temperature of the NVP source (with the carrier gas bubbling through the liquid NVP) is held at about 40° C. The lenses are treated for about 10 minutes with a pulsing glow discharge plasma (1 μsec. on, 3 μsec. off) at about 0.35 mbar pressure and about 150 Watts power.

After interrupting the glow discharge and the carrier gas flow, the reactor is continuously purged with a 20 sccm argon stream at a pressure of about 0.009 mbar for about 30 minutes, in order to remove residual monomer and activated species. The PVP coated contact lenses thus produced are highly wettable and show the following dynamic contact angles, measured with a KRUESS (Hamburg, Germany) K-12 instrument:

	Untreated	Treated
Advancing	102	38
Receding	48	23
Hysteresis	53	15

Clinical tests show that the lens does not move on the eye. See Table F for a summary of the results.

EXAMPLE F-2

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-26. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 2.8×10^{-7} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens does not move on the eye. See Table F for a summary of the results.

EXAMPLE F-3

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-27. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 9.3×10^{-7} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example

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F-1. Clinical tests show that the lens does not move on the eye. See Table F for a summary of the results.

EXAMPLE F-4

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-18. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 2.6×10^{-6} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens moves on the eye. See Table F for a summary of the results.

EXAMPLE F-5

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-16. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 1.3×10^{-5} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens moves on the eye. See Table F for a summary of the results.

EXAMPLE F-6

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-19. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 2.7×10^{-5} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens moves on the eye. See Table F for a summary of the results.

EXAMPLE F-7

Material C

A contact lens is prepared substantially in accordance with the procedure described in Example C-7. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 7.8×10^{-6} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens moves on the eye. See Table F for a summary of the results.

EXAMPLE F-8

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-13. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 1.5×10^{-6} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens does not move on the eye. See Table F for a summary of the results.

EXAMPLE F-9

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-14. Prior to

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surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 1.1×10^{-6} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens does not move on the eye. See Table F for a summary of the results.

EXAMPLE F-10

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-7. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 3.8×10^{-6} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens moves on the eye. See Table F for a summary of the results.

EXAMPLE F-11

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-6. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 8.5×10^{-6} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens moves on the eye. See Table F for a summary of the results.

EXAMPLE F-12

Material B

A contact lens is prepared substantially in accordance with the procedure described in Example B-5. Prior to surface treatment, the Ionoflux Ion Permeability Coefficient is determined to be about 7.1×10^{-5} mm²/min.

Subsequent to ion permeability measurements, the lens surface is coated with polyvinylpyrrolidone as in Example F-1. Clinical tests show that the lens moves on the eye. See Table F for a summary of the results.

TABLE F

EXAMPLE	MATERIAL (Example reference number)	IONOFUX ION PERMEABILITY COEFFICIENT* [mm ² /min]	ON-EYE MOVEMENT- CLINICAL DETERMINATION
F-1	C-25	0	NO
F-2	C-26	0.28×10^{-6}	NO
F-3	C-27	0.93×10^{-6}	NO
F-4	C-18	2.6×10^{-6}	YES
F-5	C-16	13.0×10^{-6}	YES
F-6	C-19	27.0×10^{-6}	YES
F-7	C-17	7.8×10^{-6}	YES
F-8	B-13	1.5×10^{-6}	NO
F-9	B-14	1.1×10^{-6}	NO
F-10	B-7	3.8×10^{-6}	YES
F-11	B-6	8.5×10^{-6}	YES
F-12	B-5	71.0×10^{-6}	YES

*All Ionoflux Ion Permeability Coefficients were determined on uncoat lenses.

Considering only Examples F-1 through F-13 of Table the lowest value of Ionoflux Ion Permeability Coefficient for which a lens moves on the eye is 2.6×10^{-6} mm²/min. The highest value of Ionoflux Ion Permeability Coefficient for lens which binds on the eye is 1.5×10^{-6} mm²/min. Thus, contact lens preferably has an Ionoflux Ion Permeability

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Coefficient greater than about 1.5×10^{-6} mm²/min., more preferably greater than about 2.6×10^{-6} mm²/min.

EXAMPLE G-1

Is A contact lens is prepared substantially in accordance with the procedure described in Example A-2. The Hydrodell Water Permeability Coefficient is determined to be about 0.71×10^{-6} cm²/second. Clinical tests show that the lens moves on the eye. See Table G for a summary of the results.

EXAMPLE G-2

A contact lens is prepared substantially in accordance with the procedure described in Example B-5. The Hydrodell Water Permeability Coefficient is determined to be about 1.09×10^{-6} cm²/second. Clinical tests show that the lens moves on the eye. See Table G for a summary of the results.

EXAMPLE G-3

A contact lens is prepared substantially in accordance with the procedure described in Example B-6. The lens is surface treated in a plasma gas in accordance with the procedure described in Example F-1. The Hydrodell Water Permeability Coefficient is determined to be about 0.27×10^{-6} cm²/second. Clinical tests show that the lens moves on the eye. See Table G for a summary of the results.

EXAMPLE G-4

A contact lens is prepared substantially in accordance with the procedure described in Example C-19. The lens is surface treated in a plasma gas in accordance with the procedure described in Example F-1. The Hydrodell Water Permeability Coefficient is determined to be about 0.37×10^{-6} cm²/second. Clinical tests show that the lens moves on the eye. See Table G for a summary of the results.

EXAMPLE G-5

A contact lens is prepared substantially in accordance with the procedure described in Example D-2. The Hydrodell Water Permeability Coefficient is determined to be about 1.26×10^{-6} cm²/second. Clinical tests show that the lens moves on the eye. See Table G for a summary of the results.

EXAMPLE G-6

A contact lens is prepared substantially in accordance with the procedure described in Example C-14. The Hydrodell Water Permeability Coefficient is determined to be about 0.08×10^{-6} cm²/second. Clinical tests show that the lens does not move on the eye. See Table G for a summary of the results.

TABLE G

EXAM- PLE	MATERIAL (Example reference number)	SURFACE TREAT- MENT	HYDRODELL WATER PERMEABILITY COEFFICIENT [cm ² /sec.]	ON-EYE MOVEMENT- CLINICAL DETERMI- NATION
G-1	A-2	none	0.71×10^{-6}	YES
G-2	B-5	none	1.09×10^{-6}	YES
G-3	B-6	PVP	0.27×10^{-6}	YES
G-4	C-19	PVP	0.37×10^{-6}	YES

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TABLE G-continued

EXAM- PLE	MATERIAL (Example reference number)	SURFACE TREAT- MENT	HYDRODELL WATER PERMEABILITY COEFFICIENT [cm ² /sec.]	ON-EYE MOVEMENT- CLINICAL DETERMI- NATION
G-5	D-2	none	1.26×10^{-6}	YES
G-6	C-14	none	0.08×10^{-6}	NO

Considering only Examples G-1 through G-6 of Table G, the lowest value of Hydrodell Water Permeability Coefficient for which a lens moves on the eye is 0.27×10^{-6} cm²/sec. The highest value of Hydrodell Water Permeability Coefficient for a lens which binds on the eye is 0.08×10^{-6} cm²/sec. Thus, a contact lens preferably has a Hydrodell Water Permeability Coefficient greater than about 0.08×10^{-6} cm²/sec., more preferably greater than 0.27×10^{-6} cm²/sec.

The invention has been described in detail, with reference to certain preferred embodiments, in order to enable the reader to practice the invention without undue experimentation. Theories of operation have been offered to better enable the reader to understand the invention, but such theories do not limit the scope of the invention. In addition, a person having ordinary skill in the art will readily recognize that many of the previous components, compositions, and parameters may be varied or modified to a reasonable extent without departing from the scope and spirit of the invention. Furthermore, titles, headings, example materials or the like are provided to enhance the reader's comprehension of this document, and should not be read as limiting the scope of the present invention. Accordingly, the intellectual property rights to the invention are defined by the following claims, reasonable extensions and equivalents thereof, as interpreted in view of the disclosure herein.

That which is claimed is:

1. A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high water permeability, said polymeric material being formed from polymerizable materials including:

- at least one oxyperm polymerizable material; and
- at least one ionperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionperm polymerizable material, if polymerized alone, would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec or (2) an Ionoflux Diffusion Coefficient of

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greater than about 1.5×10^{-6} mm²/min, wherein said ion permeability is measured with respect to sodium ions, said method comprising the steps of:

- (a) applying said lens to the ocular environment; and
- (b) allowing said lens to remain in intimate contact with the ocular environment for a first period of at least 24 hours.

2. A method of claim 1, further including the steps of:

- (c) removing said lens from the ocular environment;
- (d) disinfecting or cleaning said lens;
- (e) re-applying said lens to the ocular environment; and
- (f) allowing said lens to remain in intimate contact with the ocular environment for a second period of at least 24 hours.

3. A method of claim 1, wherein said first intimate contact period is at least 4 days.

4. A method of claim 2, wherein said first and second intimate contact periods are at least 4 days.

5. A method of claim 3, wherein said first intimate contact period is at least 7 days.

6. A method of claim 4, wherein said first and second intimate contact periods are at least 7 days.

7. A method of claim 5, wherein said first intimate contact period is at least 14 days.

8. A method of claim 6, wherein said first and second intimate contact periods are at least 14 days.

9. A method of claim 7, wherein said first intimate contact period is at least 30 days.

10. A method of claim 8, wherein said first and second intimate contact periods are at least 30 days.

11. An ophthalmic lens of claim 1, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

12. An ophthalmic lens of claim 11, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 6% corneal swelling.

13. An ophthalmic lens of claim 12, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 4% corneal swelling.

14. An ophthalmic lens of claim 1, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 10% corneal swelling.

15. An ophthalmic lens of claim 14, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 7% corneal swelling.

16. An ophthalmic lens of claim 15, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 5% corneal swelling.

17. A method of screening an ophthalmic lens for utility as an extended-wear lens, said method comprising the steps of:

- (a) allowing said lens to be fully hydrated by allowing said lens to equilibrate in a saline solution;

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(b) testing the lens to determine a factor which is a function of the oxygen transmissibility of said lens;

(c) testing the lens to determine a factor which is a function of the ion or water permeability of said lens; and

(d) selecting said lens as an extended-wear lens if said oxygen transmissibility factor and said water or ion permeability factor are both above predetermined limits which are established to ensure good corneal health and wearer comfort when said lens is in intimate contact with a human eye for a period of continuous, extended wear of at least 24 hours, said ion or water permeability limits being at least either (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm²/min, as measured with respect to sodium ions.

thereby ensuring said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a said extended wear.

18. A screening method of claim 17, wherein said ion permeability factor is the Ionoton Ion Permeability Coefficient.

19. A screening method of claim 18, wherein said Ionoton Ion Permeability Coefficient is greater than about 0.3×10^{-6} cm²/sec, wherein said Ionoton Ion Permeability Coefficient is measured with respect to sodium ions.

20. A screening method of claim 17, wherein said ion permeability factor is the Ionoflux Diffusion Coefficient.

21. A screening method of claim 20, wherein said Ionoflux Diffusion Coefficient is greater than about 2.6×10^{-6} mm²/min, wherein said Ionoflux Ion Permeability Coefficient is measured with respect to sodium ions.

22. A screening method of claim 17, wherein said water permeability factor is the Hydrotell Water Permeability Coefficient.

23. A screening method of claim 22, wherein said Hydrotell Water Permeability Coefficient is greater than about 0.3×10^{-6} cm²/sec.

24. A screening method of claim 19, wherein said oxygen transmissibility factor is the Dk and the limit is 70 barrers mm.

25. A screening method of claim 21, wherein said oxygen transmissibility factor is the Dk and the limit is 70 barrers mm.

26. A screening method of claim 23, wherein said oxygen transmissibility factor is the Dk and the limit is 70 barrers mm.

* * * * *

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Nicolson et al. [45] Certificate Issued Nov. 21, 2000

[54] **METHODS OF USING AND SCREENING
EXTENDED WEAR OPHTHALMIC LENSES**

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[57] **ABSTRACT**

An ophthalmic lens screening method suited for extended-wear for periods of at least one day on the eye without a clinically significant amount of corneal swelling and without substantial wearer discomfort. The lens has a balance of oxygen permeability and ion or water permeability, with the ion or water permeability being sufficient to provide good on-eye movement, such that a good tear exchange occurs between the lens and the eye. A preferred lens is a copolymerization product of a oxyperm macromer and an ionoperm monomer. The invention encompasses extended wear contact lenses, which include a core having oxygen transmission and ion transmission pathways extending from the inner surface to the outer surface.

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REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS
INDICATED BELOW.

Matter enclosed in heavy brackets [] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

ONLY THOSE PARAGRAPHS OF THE
SPECIFICATION AFFECTED BY AMENDMENT
ARE PRINTED HEREIN.

Column 11, lines 42–50:

An Ionoflux Diffusion Coefficient of greater than about $[6.4 \times 10^{-6}]$ 1.5×10^{-6} mm²/min is preferred for achieving sufficient on-eye movement. More preferably, the Ionoflux Diffusion Coefficient is greater than about 2.6×10^{-6} mm²/min, while most preferably, the Ionoflux Diffusion Coefficient is greater than about $[1.5 \times 10^{-6}]$ 6.4×10^{-6} mm²/min. It must be emphasized that the Ionoflux Diffusion Coefficient correlates with ion permeability through the lens, and thereby is a predictor of on-eye movement.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims 1 and 11–17 are determined to be patentable as amended.

Claims 2–10 and 18–26, dependent on an amended claim, are determined to be patentable.

New claims 27–35 are added and determined to be patentable.

1. A method of using a contact lens as an extended wear lens, said lens *having a surface modified by a surface treatment process*, said lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids *with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours*, said lens comprising a polymeric material which has a high oxygen permeability and a high water permeability, said polymeric material being formed from polymerizable materials including:

- (a) at least one oxypem polymerizable material; and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids.

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone, would form a hydrophilic polymer

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having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm²/min, wherein said ion permeability is measured with respect to sodium ions,

said method comprising the steps of:

- (a) applying said lens to the ocular environment; and
- (b) allowing said lens to remain in intimate contact with the ocular environment for a first period of at least 24 hours.

11. [An ophthalmic lens] A method of claim 1, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

12. [An ophthalmic lens] A method of claim 11, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 6% corneal swelling.

13. [An ophthalmic lens] A method of claim 12, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 4% corneal swelling.

14. [An ophthalmic lens] A method of claim 1, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 10% corneal swelling.

15. [An ophthalmic lens] A method of claim 14, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 7% corneal swelling.

16. [An ophthalmic lens] A method of claim 15, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 5% corneal swelling.

17. A method of screening an ophthalmic lens for utility as an extended-wear lens *having a surface modified by a surface treatment process*, said method comprising the steps of:

- (a) allowing said lens to be fully hydrated by allowing said lens to equilibrate in a saline solution;
- (b) testing the lens to determine a factor which is a function of the oxygen transmissibility of said lens;
- (c) testing the lens to determine a factor which is a function of the ion or water permeability of said lens; and

(d) selecting said lens as an extended-wear lens if said oxygen transmissibility factor and said water or ion permeability factor are both above predetermined limits which are established to ensure good corneal health and wearer comfort when said lens is in intimate contact with a human eye for a period of continuous, extended wear of at least 24 hours *with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of extended wear*, said ion or water permeability limits being at least either (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm²/min, as measured with respect to sodium ions, thereby ensuring said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during [a] said extended wear.

27. A method of using a contact lens as an extended wear lens, said lens, said lens having ophthalmically compatible

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inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of wear, said lens comprising a polymeric material which has a high oxygen permeability equal to or greater than about 69 barrers and a high water permeability, said polymeric material being formed from polymerizable materials including:

- (a) at least one oxyperm polymerizable material; and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone, would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 8.0×10^{-6} cm²/sec, wherein said ion permeability is measured with respect to sodium ions, and

wherein said lens is autoclaved without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement,

said method comprising the steps of:

- (a) applying said lens to the ocular environment; and
- (b) allowing said lens to remain in intimate contact with the ocular environment for a first period of at least 24 hours.

28. A method of screening an ophthalmic lens for utility as an extended-wear lens, said method comprising the steps of:

- (a) allowing said lens to be fully hydrated by allowing said lens to equilibrate in a saline solution;
- (b) testing the lens to determine a factor which is a function of the oxygen transmissibility of said lens;
- (c) testing the lens to determine a factor which is a function of the ion or water permeability of said lens; and

- (d) selecting said lens as an extended-wear lens if said oxygen transmissibility factor and said water or ion permeability factor are both above predetermined limits which are established to ensure good corneal health and wearer comfort when said lens is in intimate contact with a human eye for a period of continuous, extended wear of at least 24 hours with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of extended wear, said ion or water permeability limits being at least an

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Ionoton Ion Permeability Coefficient of greater than about 8.0×10^{-6} cm²/sec, as measured with respect to sodium ions,

thereby ensuring said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during said extended wear,

wherein said lens is autoclaved without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement.

29. A method of using a contact lens as an extended wear lens, said lens having a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear, said lens comprising a polymeric material which has a high oxygen permeability equal to or greater than about 69 barrers and a high water permeability, said polymeric material being formed from polymerizable materials including:

- (a) at least one oxyperm polymerizable material; and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone, would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 75 barrers/mm and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 250.0×10^{-6} cm²/sec, wherein said ion permeability is measured with respect to sodium ions, and

wherein said lens is autoclaved without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement,

said method comprising the steps of:

- (a) applying said lens to the ocular environment; and
- (b) allowing said lens to remain in intimate contact with the ocular environment for a first period of at least 7 days.

30. A method of screening an ophthalmic lens for utility as an extended-wear lens having a surface modified by a surface treatment process, said method comprising the steps of:

- (a) allowing said lens to be fully hydrated by allowing said lens to equilibrate in a saline solution;
- (b) testing the lens to determine a factor which is a function of the oxygen transmissibility of said lens;

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- (c) testing the lens to determine a factor which is a function of the ion or water permeability of said lens; and
- (d) selecting said lens as an extended-wear lens if said oxygen transmissibility factor and said water or ion permeability factor are both above predetermined limits which are established to ensure good corneal health and wearer comfort when said lens is in intimate contact with a human eye for a period of continuous, extended wear of at least 7 days with having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of wear; said ion or water permeability limits being at least an Ionoton Ion Permeability Coefficient of greater than about $250.0 \times 10^{-6} \text{ cm}^2/\text{sec}$, as measured with respect to sodium ions,
- thereby ensuring said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during said extended wear.

31. A method of using a contact lens as an extended wear lens, said lens having a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of wear; said lens comprising a polymeric material which has a high oxygen permeability equal to or greater than about 72 barrers and a high water permeability, said polymeric material being formed from polymerizable materials including:

- (a) at least one oxyporm polymerizable material; and
- (b) at least one ionoporm polymerizable material,
- wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids,
- wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,
- wherein said ionoporm polymerizable material, if polymerized alone, would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and
- wherein said ophthalmic lens has an oxygen transmissibility of at least about 81 barrers/mm and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about $350.0 \times 10^{-6} \text{ cm}^2/\text{sec}$, wherein said ion permeability is measured with respect to sodium ions,
- said method comprising the steps of:
- (a) applying said lens to the ocular environment; and
- (b) allowing said lens to remain in intimate contact with ocular environment for a first period of at least 24 hours.

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32. A method of screening an ophthalmic lens for utility as an extended-wear lens having a surface modified by a surface treatment process, said method comprising the steps of:

- (a) allowing said lens to be fully hydrated by allowing said lens to equilibrate in a saline solution;
- (b) testing the lens to determine a factor which is a function of the oxygen transmissibility of said lens;
- (c) testing the lens to determine a factor which is a function of the ion or water permeability of said lens; and
- (d) selecting said lens as an extended-wear lens if said oxygen transmissibility factor and said water or ion permeability factor are both above predetermined limits which are established to ensure good corneal health and wearer comfort when said lens is in intimate contact with a human eye for a period of continuous, extended wear of at least 30 days with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of wear; said lens having said ion or water permeability limits being at least an Ionoton Ion Permeability Coefficient of greater than about $350.0 \times 10^{-6} \text{ cm}^2/\text{sec}$, as measured with respect to sodium ions,

thereby ensuring said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during said extended wear.

33. A method of using a contact lens as an extended wear lens, said lens having a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of wear; said lens comprising a polymeric material which has a high oxygen permeability equal to or greater than about 69 barrers and a high water permeability, said polymeric material being formed from polymerizable materials including:

- (a) at least one oxyporm polymerizable material; and
- (b) at least one ionoporm polymerizable material,
- wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids,
- wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,
- wherein said ionoporm polymerizable material, if polymerized alone, would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration,
- wherein said lens is subject to having a manufacturing technique without lowering either said oxygen permeability below levels sufficient to maintain good corneal health, and

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wherein said ophthalmic lens has an oxygen transmissibility of at least about 75 barrers/mm and an ion permeability characterized by an Ionoflux Diffusion Coefficient of greater than about 13.0×10^{-6} mm²/min, wherein said ion permeability is measured with respect to sodium ions, 5

said method comprising the steps of:

- (a) applying said lens to the ocular environment; and
- (b) allowing said lens to remain in intimate contact with the ocular environment for a first period of at least 24 hours. 10

34. A method of screening an ophthalmic lens for utility as an extended-wear lens having a surface modified by a surface treatment process, said method comprising the steps of: 15

- (a) allowing said lens to be fully hydrated by allowing said lens to equilibrate in a saline solution;
- (b) testing the lens to determine a factor which is a function of the oxygen transmissibility of said lens; 20
- (c) testing the lens to determine a factor which is a function of the ion or water permeability of said lens; and
- (d) selecting said lens as an extended-wear lens if said oxygen transmissibility factor and said water or ion

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permeability factor are both above predetermined limits which are established to ensure good corneal health and wearer comfort when said lens is in intimate contact with a human eye for a period of continuous, extended wear of at least 30 days with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of wear, said ion or water permeability limits being at least an Ionoflux Diffusion Coefficient of greater than about 6.4×10^{-6} mm²/min, as measured with respect to sodium ions,

thereby ensuring said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during said extended wear.

35. A screening method of claim 29, 31, or 34, wherein said lens is produced by a manufacturing method without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement.

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